

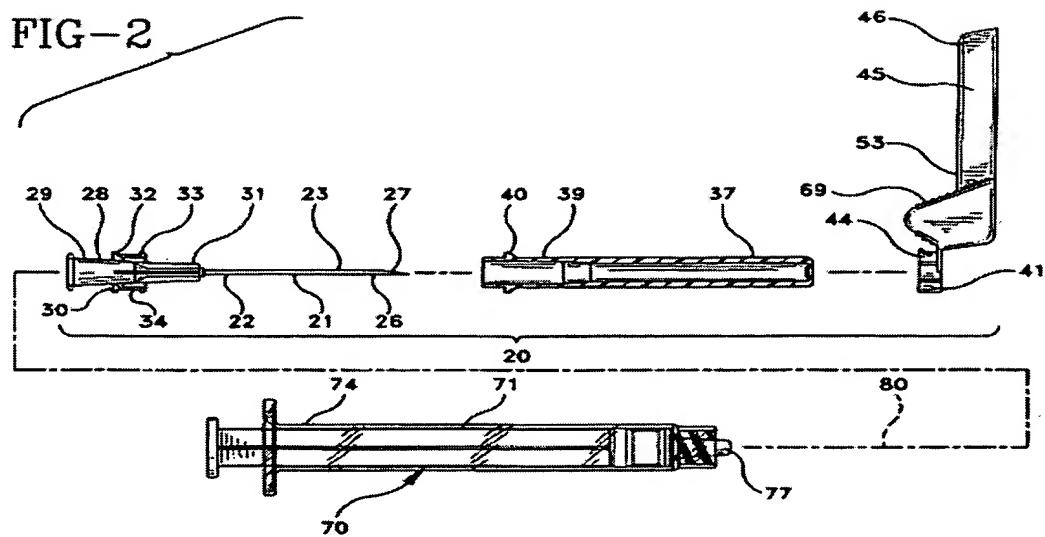
REMARKS

This application has been reviewed in light of the Office Action dated October 5, 2004. Claims 1-9, 11 and 14-90 are pending in the application. Claims 21, 22, 24, 26, 32-59, 61, 66-68, 73-90 and 93 are withdrawn. Claims 1, 69 and 72 are amended in a manner that Applicants believe overcome the rejections in the Office Action. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicants are believed to be entitled. Applicants submit that no new matter or issues are introduced by the amendments. Claim 2 is cancelled without prejudice. Claims 10, 12, 13, 91 and 92 were previously cancelled without prejudice. Applicants reserve the right to prosecute the subject matter of any cancelled claims in continuing applications.

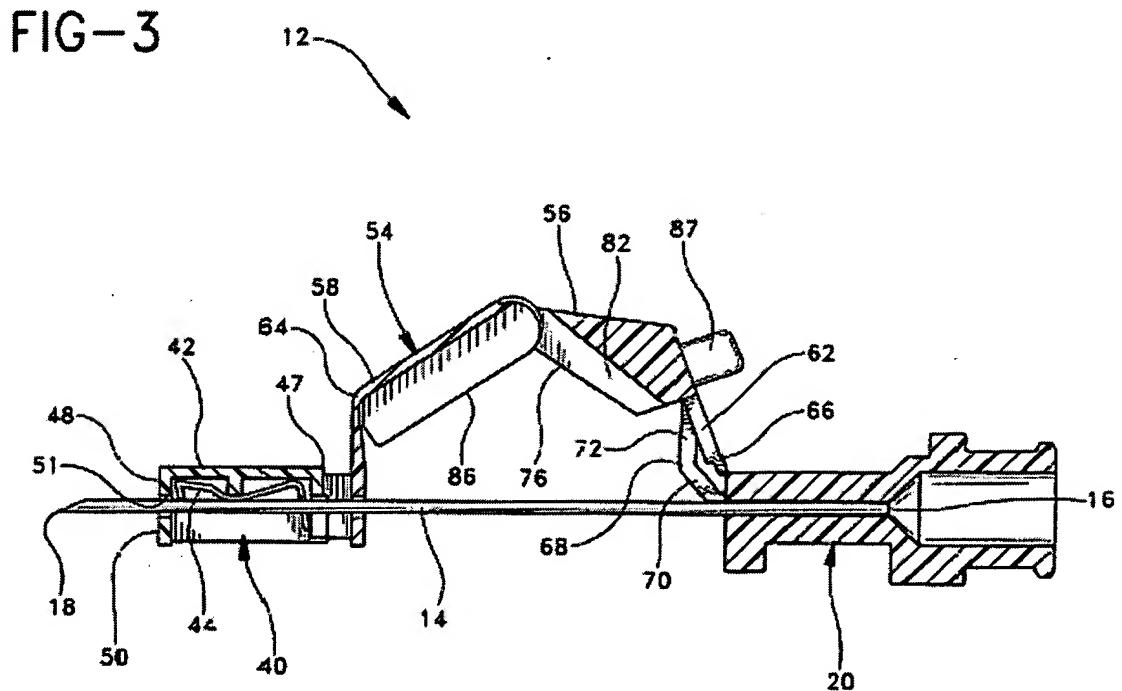
Initially, Applicants gratefully acknowledge the allowability of the subject matter recited in claims 3, 8-9, 20 and 71. Applicants, however, respectfully submit that in view of the amendments and remarks herein, all claims presently pending in the application are allowable over the art of record.

In the Office Action, claims 1-2, 4-7, 11, 14-19, 23, 25, 27-31, 60, 62-65, 69-70 and 72 of the present application were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,665,075 to Gyure et al. (Gyure '075) in view of U.S. Patent No. 5,348,544 to Sweeney et al. (Sweeney '544). However, it is respectfully submitted that amended independent claim 1, independent claim 5, claims 6, 7, 11, 14-19, 23, 25, 27-31, 60, 62-65 ultimately depending therefrom, amended independent claim 69, claim 70 depending therefrom and amended independent claim 72, clearly and patentably distinguish over the Gyure '075 patent in any combination with the Sweeney '544 patent. Claim 2 is cancelled.

Referring to FIG. 2 reproduced below, the Gyure '075 patent shows a pivoting needle shield 45 formed with a collar 41. (col. 4, lines 42-48).



Referring to FIG. 3 reproduced below, the Sweeney '544 patent shows a shieldable needle assembly 12 articulated to an outer surface of a needle hub 20 (col. 4, lines 27-39).



In contrast, amended claim 1 of the present application recites “[a] medical needle shield apparatus comprising: a monolithic needle hub, a collar extending distally from the needle hub;

and a shield having a proximal end receivable by an interior cavity of the collar in an interlocking engagement and including a plurality of hingedly connected segments, the shield being extensible between a retracted position and an extended position.”

Claim 5 of the present application recites, *inter alia*, “[a] medical needle shield apparatus comprising … the proximal end of the shield being receivable within the interior cavity of the collar in an interlocking engagement …”

Amended claim 69 of the present application recites, *inter alia*, “[a] medical needle shield apparatus comprising … a shield means, having a proximal end … for engaging the interior cavity of the collar of the needle hub means in an interlocking engagement …”

Amended claim 72 of the present application recites, *inter alia*, “[a] medical needle shield apparatus comprising … the proximal end of the shield being receivable by an interior cavity of the collar in an interlocking engagement …”

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580, 582 (CCPA 1974); see also *CFMT Inc. v. Yieldup International Corp.*, 68 USPQ2d 1940, 1947 (Fed. Cir. 2003) and *Leinoff v. Louis Milona & Sons, Inc.*, 220 USPQ 845 (Fed. Cir. 1984). In the Office Action (at page 3, first paragraph), the Examiner acknowledges that the cited Gyure '075 patent does not include all of the claim limitations of the presently pending claims, stating that “Gyure … fails to include the proximal end of the needle shield being received within the cavity of the needle hub collar.” Therefore, because the Gyure '075 patent fails to disclose or suggest, *inter alia*, the claim limitation of “a shield having a proximal end receivable by an interior cavity of the collar in an interlocking engagement” the Examiner has not established a *prima facie* case of obviousness.

The Examiner further alleges (at page 3, second paragraph of the Office Action) that “… it would have been obvious to rearrange the parts … of Gyure …” However, “[t]he mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant’s specification, to

make the necessary changes in the reference device.” *Ex parte Chicago Rawhide Manufacturing Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984). As acknowledged by the Examiner and discussed above, the Gyure ‘075 patent does not include, *inter alia*, “a shield having a proximal end receivable by an interior cavity of the collar in an interlocking engagement.” Further, the Sweeney ‘544 patent does not include, *inter alia*, “a shield having a proximal end receivable by an interior cavity of the collar in an interlocking engagement.” The Sweeney ‘544 patent merely shows a shield having a hinge formed with the outer surface of a needle hub, as discussed above. Contrary to the allegations contained in the Office Action, the references cited do not provide a motivation or reason for one skilled in the art, without the benefit of the present application, to make, *inter alia*, “a shield having a proximal end receivable by an interior cavity of the collar in an interlocking engagement.”

Therefore, the Gyure ‘075 patent and the Sweeney ‘544 patent in no way disclose or suggest structure as recited in claims 1, 5, 69 and 72. The Sweeney ‘544 patent does not cure the deficiencies of the Gyure ‘075 patent in that the Gyure ‘075 patent and the Sweeney ‘544 patent do not disclose, *inter alia*, a medical needle shield apparatus having a needle hub, a collar, and a shield having a proximal end receivable by an interior cavity of the collar in an interlocking engagement.

The Examiner further alleges (at page 3, second paragraph of the Office Action) that “... applicant has not disclosed that having the proximal end of the shield locking into the cavity of the collar provides an advantage, is used for a particular purpose, or solves a stated problem.” Applicant respectfully disagrees. The shield of the present disclosure having a proximal end receivable by an interior cavity of the collar in an interlocking engagement has several advantages and solves a variety of drawbacks over the prior art. For example, as stated on: page 12, lines 8-12; and page 15, lines 14-19 of the present application, the present disclosure provides the advantages of applicability to various needle shield apparatus, facile attachment between a shield and a hub, cost savings in manufacture, convenient and safe manipulation of medical needle devices, etc.

Because of the above distinctions and advantages of the present disclosure, it is respectfully submitted that amended independent claim 1, independent claim 5, claims 6, 7, 11, 14-

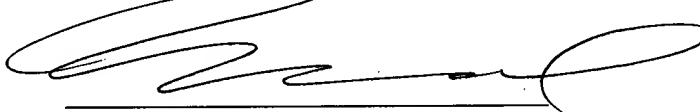
19, 23, 25, 27-31, 60, 62-65 ultimately depending therefrom, amended independent claim 69, claim 70 depending therefrom and amended independent claim 72 are patentable and not obvious over the Gyure '075 patent in any combination with the Sweeney '544 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1, 3-9, 11 and 14-90 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Please charge any deficiency as well as any other fee(s) that may become due at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-0369. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-0369 therefor.

Respectfully submitted,



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